

CLAIMS

We claim:

5 1. A method for treating a human patient afflicted with cancer, comprising administering therapeutically effective amounts of temozolomide and irinotecan to such a patient for a time period sufficient to effect at least a partial tumor response.

10 2. The method of claim 1, wherein the irinotecan is in the form of a hydrochloride salt.

15 3. The method of claim 1, wherein the temozolomide and irinotecan are administered over repeated 21 day cycles, where said 21 day cycles are divided into three 1 week periods.

20 4. The method of claim 3, wherein the total amount of irinotecan administered over the 21 day period ranges from 3 to 400 mg/m² of the patient's body surface.

25 5. The method of claim 3, wherein the amount of temozolomide administered over the 21 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 21 day period.

30 6. The method of claim 3, wherein the amount of temozolomide administered over the 21 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 21 day period and the irinotecan is in the form of a hydrochloride salt.

7. The method of claim 3, wherein the irinotecan is administered for 5 consecutive days at a daily dose of 10 to 40 mg/m²/day during the first week and for 5 consecutive days at a daily dose of 10 to 40 mg/m²/day during the second week, followed by the third week in which irinotecan is not administered.

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8. The method of claim 7, wherein the temozolomide is administered for 5 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first week, followed by the second and third week in which temozolomide is not administered.

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9. The method of claim 7, wherein the temozolomide is administered for 5 to 7 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first and third weeks of the 21 day cycle.

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10. The method of claim 7, wherein the temozolomide is administered for 5 to 7 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first and second weeks of the 21 day cycle.

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11. The method of claim 9, wherein the irinotecan is in the form of a hydrochloride salt.

12. The method of claim 10, wherein the irinotecan is in the form of a hydrochloride salt.

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13. The method of claim 3, wherein the irinotecan is administered on a single day of the 21 day cycle in an amount of from 250 to 650 mg/m².

14. The method of claim 3, wherein the irinotecan is administered once a week during the 21 day cycle at a dose of from 100 to 125 mg/m².

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15. The method of claim 3 wherein the temozolomide and irinotecan are both administered on the first day of the 21 day treatment cycle.

16. The method of claim 15, wherein the irinotecan is in the form of a hydrochloride salt.

5 17. The method of claim 1, wherein the temozolomide is administered prior to the administration of the irinotecan.

10 18. The method of claim 3, wherein the temozolomide and irinotecan are administered in three 21 day cycles, each cycle having a dosing period wherein the temozolomide is administered for the first five days of the 21 day cycle at a daily dose of 50 to 200 mg/m²/day, the irinotecan is administered with the temozolomide for the first 5 days of the 21 day cycle and for an additional 5 day period during the second week of the 21 day cycle at a daily dose of 10 to 40 mg/m²/day, followed by the third week in which temozolomide and irinotecan is 15 not administered.

19. The method of claim 17, wherein the temozolomide is administered orally and the irinotecan is administered intravenously.

20 20. The method of claim 1, wherein the temozolomide and irinotecan are administered over repeated 28 day cycles.

21. The method of claim 20, wherein the total amount of irinotecan administered over the 28 day period ranges from 3 to 400 mg/m² of the patient's body surface.

22. The method of claim 20, wherein the amount of temozolomide administered over the 28 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days 30 over the 28 day period.

23. The method of claim 20, wherein the amount of temozolomide administered over the 28 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 28 day period and the irinotecan is in the form of a hydrochloride salt.

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24. The method of claim 20, wherein temozolomide and irinotecan are administered over a 28 day cycle, wherein the temozolomide is administered on days 1-14 of said cycle at a daily dose of 75 to 150 mg/m²/day and wherein the irinotecan is administered on day 8 of said cycle at a daily dose of 100 to 350 mg/m²/day.

10 25. The method of claim 24, wherein the temozolomide is administered orally and the irinotecan is administered intravenously

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26. A medical kit for treating a cancer patient is provided, comprising:

- (a) a supply of temozolomide;
- (b) a supply of irinotecan; and
- (c) printed instructions for administering temozolomide and irinotecan to a cancer patient.